



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,143	01/17/2006	Giuseppe Alvaro	PI4861USW	5582
23347 7590 02/13/2009 GLAXOSMITHKLINE CORPORATE INTELLECTUAL PROPERTY, MAI B482 FIVE MOORE DR., PO BOX 13398 RESEARCH TRIANGLE PARK, NC 27709-3398				
EXAMINER				
CHANG, CELIA C				
ART UNIT		PAPER NUMBER		
1625				
NOTIFICATION DATE		DELIVERY MODE		
02/13/2009		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USCIPRTP@GSK.COM

LAURA.M.MCCULLEN@GSK.COM

JULIE.D.MCFALLS@GSK.COM

Office Action Summary

Application No.

10/520,143

Applicant(s)

ALVARO ET AL.

Examiner

Celia Chang

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 13 and 15-20 is/are pending in the application.
- 4a) Of the above claim(s) 18-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-9, 13, 15-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's election without traverse of Group I, claim 8 and claims 1-7, 9, 13, 15-17 reading on n=1 compounds in the reply filed on Nov. 24, 2008 is acknowledged.

Claims 10-12, 14 have been canceled. Claims 1-9, 13, 15-17 reading on n=1 compounds are prosecuted. Claims 18-20 and the remaining subject matter of claim 7, being drawn to the nonelected invention are withdrawn from consideration per 37 CFR 1.142(b).

2. Claims 1 and 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims encompassed the scope of "solvates of the compounds" for which no description or enabling support can be found in the specification. Please note that each solvate is a different "chemical identity" and there should never be any doubt in this century as to the chemical identity of a material (see Suddon). Unlike formation of salts between a pharmaceutically acceptable acid and an organic base compound of the claims, the formation of "solvates" must find descriptive and enabling support for such claimed scope because absent of specific description, one having ordinary skill in possession of compounds would not be able to offer any predictability of which one will form what solvate (see Braga p.3640). A survey of the specification indicated there is no description of which solvent can form solvate with the compounds, under what condition will such solvates be obtained, and whether the solvates will have consistent properties to be considered inclusive as being a "Markush" alternative of the compounds.

No examples, no process of making, no starting material or operability can be found for any compound encompassed by the Markush formula to have the ability in forming what solvate. Therefore, absent of description and enabling disclosure, the specification is insufficient in supporting the "claimed" scope of "solvates of the compounds".

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-9, 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hobbs et al. US 6,887,889 in view of Rajagopal et al.; Thathagar et al. or Gallon et al.

Determination of the scope and content of the prior art (MPEP §2141.01)

Hobbs et al. '889 generically disclosed the claimed compounds, see col. 22, formula at lines 35 with example 10 at col. 33; col. 23, formula at lines 25, with example 15 at col. 41; and generic examples of the R1 moieties in table 1. Structural analogous compounds

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the exemplified compounds (see schemes 8 and 9 col. 22-23) and the instant claims is that instead of iodo-substitution on the phenyl ring i.e. the proviso compound, the instant claims are drawn to chloro-, bromo-, fluoro- or dihalo-substituted phenyl compounds. The intermediates of the Hobbs et al. are disclosed to be material for making the final product through the Suzukin coupling procedure. Rahagopal et al. (see fig. 1), Gallon et al. (see p.7253) or Thathagar et al. (p.11859) disclosed that other halogen substituted aromatic material will equally operable in making the biphenyl derivatization wherein the intermediates are processed.

Finding of prima facie obviousness—rational and motivation (MPEP§2142-2143)

It is prima facie obvious to prepare alternative halogen analogs of the iodo-species disclosed by Hobbs et al. '889 using chloro-, bromo- or dihalo-substitution because the generically disclosed material by Hobbs et al. are for Suzuki coupling reaction wherein chloro-, bromo- or dihalo-substitution are alternative choices for such material. It is a design choice for one skilled in the art in possession of the operable iodo-substituted material to modify the iodo- with other halogen substitution at multiple position with expectation of operability and guided the generic scope of the reference.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hobbs et al. US 6,887,889 in view of Janssen et al. US 3,097,209.

The finding of the claimed compounds *prima facie* obvious over Hobbs et al. '889 is also applicable here and incorporated by reference. Although Hobbs' compounds are intermediates for making final products, analogous compounds of Hobbs' intermediates have been known to have pharmacological activity see i.e. US '209 for selective anti-vomiting effect. Therefore it is *prima facie* obvious when in possession of the compounds, one would be in possession of the pharmaceutical composition knowing its utility in biological activity.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Feb. 9, 2009

/Celia Chang/
Primary Examiner
Art Unit 1625